UNITED STATES PATENT APPLICATION

FOR

DEVICE FOR RESECTION OF TISSUE

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SPECIFICATION

TITLE OF INVENTION

DEVICE FOR RESECTION OF TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 U.S.C. §120 to, and incorporates by reference herein in its entirety, co-pending United States Provisional Patent Application Serial Number _____, filed _____, by inventor Michael D. Laufer, M.D., entitled "NOVEL DEVICE FOR RESECTION OF TISSUE.".

FIELD OF THE INVENTION

[0002] The present invention relates to medical devices. More particularly, the present invention relates to a medical device for the excision of tissue.

BACKGROUND OF THE INVENTION

[0003] Almost everyone experiences a little acid reflux, particularly after meals. Acid reflux irritates the walls of the esophagus, inducing a secondary peristaltic contraction of the smooth muscle, and may produce the discomfort or pain known as heartburn. Many people experience heartburn at least once a month and most episodes of acid reflux are asymptomatic. However, patients with a condition known as chronic gastroesophageal reflux disease ("GERD"), suffer from severe heartburn.

[0004] After a meal, the lower esophageal sphincter ("LES") usually remains closed. When it relaxes, it may allow acid, partially digested foodstuff, and the like to reflux into the esophagus. Patients with GERD experience an increased number of transient LES relaxations, which are the dominant cause of reflux episodes. As the number of transient LES relaxations increases, the frequency of reflux episodes increases, thereby increasing the cumulative amount of time gastric acid spends in the esophagus. GERD symptoms are present weekly in nearly 20% of adults and daily in about 10% of adults.

[0005] Another factor that increases esophageal acid exposure time in patients with GERD is ineffective esophageal clearance. Although peristalsis (the movement of the esophagus, induced by swallowing, in which waves of alternate circular contraction and relaxation propel the contents onward) occurs, esophageal clearance is ineffective because of decreased amplitude of secondary peristaltic waves.

[0006] These gastric acids and other refluxing materials can cause irritation to the lower esophagus that in turn results in changes to the tissue. These changes, called metaplasia, are seen micro and macroscopically and if left unchecked can result in cancer of the esophagus. The pre-cancerous condition of metaplasia in the esophagus is known as Barrett's esophagus ("B.E."). B.E. may also result from the abnormal tissue repair in the setting of chronic GERD.

[0007] The only reliable way to diagnose B.E. is for a patient to undergo yearly endoscopy and biopsy to detect "gastric- or intestinal-appearing mucosa." B.E. is found in 12% of patients undergoing endoscopy for GERD. Of that percentage, the risk of esophageal cancer ("EC") is 50 to 100 times higher than other people who do not have B.E. The incidence of EC has increased at a rate faster than any other cancer. In fact, EC is the eighth most common cancer in the world.

[0008] There are no drugs or surgery that produce consistent regression of B.E. B.E. is currently treated by repeated frequent biopsies and cutting and removing the affected section of the esophagus. If cancer is detected in the biopsies, the stomach is pulled up into the chest to connect with the shorter remaining stump of esophagus connected to the mouth. This procedure has serious consequences and disadvantages for patients, may need to be performed several times in a patient's lifetime, and is quite costly.

[0009] Thus, there is a need for an apparatus and method to excise affected tissue without having a patient undergo a painful, complicated, risky, and difficult surgery. Moreover, there is a need for an apparatus and method that can resect affected tissue from a body part, such as an esophagus, while leaving the structural elements of the body part intact.

BRIEF DESCRIPTION OF THE INVENTION

[0010] The present invention provides for an apparatus and method to excise a tissue sample having a conducting element configured to receive power, an insulating holder coupled to said conducting element, and a connector coupled to said insulating holder for connection to a medical device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The accompanying drawings, which are incorporated into and constitute a part of this specification, illustrate one or more embodiments of the present invention and, together with the detailed description, serve to explain the principles and implementations of the invention.

[0012] In the drawings:

Fig. 1a is an illustration of a resection device in accordance with one embodiment of the present invention.

Fig. 1b is an illustration of the conducting element.

Fig. 2 illustrates the resection device removably attached to an endoscope.

Fig. 3 is an illustration of an example to removably attach the resection device connected to an endoscope in accordance with one embodiment of the present invention.

Fig. 4 is an illustration of the resection device in an esophagus.

Fig. 5 is a block diagram illustrating a method of the present invention.

DETAILED DESCRIPTION

[0013] Embodiments of the present invention are described herein in the context of a device for resection of tissue. Those of ordinary skill in the art will realize that the following detailed description of the present invention is illustrative only and is not intended to be in any way limiting. Other embodiments of the present invention will readily suggest themselves to such skilled persons having the benefit of this disclosure. Reference will now be made in detail to implementations of the present invention as illustrated in the accompanying drawings. The same reference indicators will be used throughout the drawings and the following detailed description to refer to the same or like parts.

[0014] In the interest of clarity, not all of the routine features of the implementations described herein are shown and described. It will, of course, be appreciated that in the development of any such actual implementation, numerous implementation-specific decisions must be made in order to achieve the developer's specific goals, such as compliance with application- and business-related constraints, and that these specific goals will vary from one implementation to another and from one developer to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking of engineering for those of ordinary skill in the art having the benefit of this disclosure.

[0015] According to embodiments of the present invention, an apparatus and method to resect affected tissue from a body part, such as an esophagus, while leaving the structural elements of the body part intact is disclosed. Fig. 1a is an illustration of a resection device in accordance with one embodiment of the present invention. The resection device, generally numbered as 10, has a conducting element 12 mounted within an insulating holder 14. The conducting element 12 may be mounted within the insulating holder 14 with epoxy or any other similar material. The conducting element 12 may be made of any conducting material and the insulating holder 14 may be made of any heat-resistant and electrically insulating material. In one embodiment of the present invention, the conducting material 12 may be a wire made of tungsten and the insulating holder 14 may be made of ceramic. In another embodiment, the insulating holder 14 may be made of injection molded plastic. The distance *d* between the conducting element 12 and the insulating holder 14 determines the depth of tissue cut.

[0016] A connector 16 may be fixedly attached to the insulating holder 14 to connect the resection device 10 to a medical instrument such as an endoscope. The connector 16 is fixedly attached to one end of the insulating holder 14. However, as illustrated in Figs. 2 and 3, the connector 28 may be fixedly attached to the center of the insulating holder 14 or other position. Thus, the position of the connector 16 is not intended to be limiting.

[0017] Fig. 1b is an illustration of the conducting element. The conducting element 12 is formed with many microfractures 18 along the top 22 of the conducting

element 12. The microfractures 18 serve as current density concentration points to form plasma when the resection device 10 is activated. The plasma acts to facilitate hemostasis of blood vessels and to separate the affected tissue from its tissue bed, thereby having the ability to cut strips of mucosa as further discussed below. The strips may then be removed and evaluated for cancerous cells. Current surgical ablation technologies do not allow for the removal of tissue for evaluation since the tissues are destroyed *in situ* without removing a sample of tissue.

[0018] The microfractures 18 may be formed by bending the conducting element 12 along an arc 20 having a radius of less than 5cm. The conducting element 12 should not be pre-heated or annealed. In one embodiment, the conducting element 12 is bent at room temperature. The corners 24a, 24b, 24c, 24d of the conducting element 12 may be bent to an angle of up to 90° to facilitate connection to the insulating holder 14.

[0019] Fig. 2 illustrates the resection device removably attached to an endoscope. The resection device 10 may be removably attached to an optical endoscope 32 such as a fiber optic, charge coupled device, or any other similar endoscope. The connector 28 may be removably affixed to the working channel 30 of the endoscope 32 by any means such as twisting, friction fit, screws, or any other similar means. The connector may be made of an elastomeric material.

[0020] Fig. 3 is an illustration of an example to removably and flexibly attach the resection device connected to an endoscope in accordance with one embodiment of the

present invention. Fig. 3 illustrates the use of a wing nut 40 to removably attach the resection device 10 to the endoscope 32. The wing nut 40 may be turned to bring in the pulling nut 42 closer to the wing nut 40. As a result, the connector may bow or bulge.

[0021] Referring back to Fig. 2, the resection device 10 may have an electrical connection fixedly attached to the conducting element 12 to form the plasma. The electrical connection may be formed by a wire enforcement member (not shown) adjacent the first end 44 of the endoscope or by having an electrical wire 26 inserted through a lumen 34 within the endoscope 32. The electrical wire 26 may then exit an exit port 46 and be connected to a power source 36. In one embodiment, the power source 36 may supply radio frequency power.

[0022] As current is created by the electrical connection and the resection device 10 is moved between the layers of mucosa, steam is created. Tissue is dissected utilizing the steam that is created by the resistive heating of the conducting element 12 and/or the plasma field. It has been determined that the impedance of the mucosa and submucosa is different, possibly due to the greater percentage of moisture within the mucosa. This moisture difference results in a higher impedance in the submucosa and therefore less current flow to the submucosa. It is this impedance difference that allows the resection device to cut through the affected tissue and not damage the submucosa. However, a user will need to monitor and ensure that when the resection device is active, it is moving and not immobile, even for a few seconds, to avoid damage to the submucosa.

[0023] Moreover, as long as steam is created, the temperature should be no greater than about 100°C. Should the steam dissipate, causing the temperature to rise over 100°C, it is an indication that the resection device is cutting into the deeper tissue of the body part and will cause damage or injury. As further discussed below, the temperature may be monitored using a temperature-sensing device.

[0024] A spring tension device 48 and friction tension device 50 may be positioned adjacent the exit port 46. In use, the electrical wire 26 is pulled out through the spring tension device 48 and friction tension device 50 until the resection device 10 is held adjacent the first end 44 while the endoscope 32 is in a straight position. The friction tension device 50 may then be actuated to secure the electrical wire 26 from withdrawing back into the endoscope 32 and out the first end 44. When the endoscope 32 is flexed, the spring tension device 48 may be compressed and the tension on the electrical wire 26 and resection device 10 may then be maintained. This allows the resection device to be flexibly attached to the distal end of the endoscope with the resection device maintained in position by tension on the attached wire as it is pulled back by the compressed spring.

[0025] The radio frequency power may be supplied in either a bipolar fashion with the electrical wire 26 serving as one electrode. However, the power may be supplied in a monopolar fashion where the electrical wire 26 is one pole and the patient 52 (Fig. 4) is connected to the other circuit with a grounding plate 58.

[0026] Embodiments of the present invention may be used with other devices to enhance the performance of the resection device. A vibrating mechanism 38 may be removably attached to the resection device to increase the efficiency of separating the affected tissue from its tissue bed. The vibrating mechanism 38 may be a mechanical rotating vibrator or an ultrasonic vibrating crystal. As illustrated in Fig. 2, if a mechanical rotating vibrator is used, the mechanical rotating vibrator may be removably attached to the electrical wire 26. However, if an ultrasonic vibrating crystal is used, it may be integrated into the resection device 10 and coupled to the conducting element 12.

[0027] Various medical instruments may be removably attached or connected to the resection device to ensure accurate movement or incision of the resection device to prevent inadvertent perforation of non-affected tissue or body parts. Medical instruments that may be used to sense, monitor, and/or ensure movement of the resection device are temperature sensing devices, impedance sensing devices, direct motion sensing device, indirect motion sensing devices, mechanical pullers and/or pushers, and visualization as further described below.

[0028] Temperature sensing devices, such as a thermocouple or thermistor, may be attached to the conducting element. The temperature-sensing device may be programmed to reduce or stop the RF circuit when a certain temperature is reached. For the excision of the mucosa in the esophagus, it was determined that a temperature range of about 70°C and 100°C worked best. As discussed above, the temperature should not exceed about 100°C to prevent injury or damage to deeper structures of the body part.

[0029] As discussed above, the resection device should continually be moving if activated to prevent injury to deeper structures of the body part. Thus, an impedance-sensing device may also be used to ensure accurate movement of the resection device. The impedance-sensing device may detect the impedance of the RF circuit as current courses through the resection device. If the resection device is activated but not moved through the affected tissue, the impedance rises in a nearly linear fashion as the tissue desiccates to indicate that the RF circuit is interrupted. In the alternative, if the impedance increases and decreases, it is an indication that the RF circuit is not interrupted and the resection device is moving. The waveform may be analyzed by Fast Fourier Transform, with the frequency breakpoint shifting as the device is moved. If the device is not moving, the frequency breakpoint does not appreciably shift.

[0030] A wheel may also be attached to the resection device through the electrical wire to detect movement of the resection device. The wheel moves as the resection device is moving, and the wheel stops when the resection device stops moving. Should the wheel stop moving, it is an indication that the RF circuit is to be interrupted to prevent deeper tissue injury or perforation. Such feedback is provided to the RF generator controller.

[0031] A mechanical pull or pusher device may also be used to detect movement of the resection device. The pull or pusher device may be attached to the endoscope. Power will flow to the resection device if tension is applied to the endoscope sufficient to

push or pull the mechanical pull or pusher device. If tension is reduced to below a certain level, the RF may be made to stop thereby stopping cutting of the resection device.

[0032] A power control box may also be positioned between the power source and resection device. The power control box provides for an additional safely measure by controlling the current or RF flow to the conducting element. In one embodiment, the power control box provides greater power initially to start a cut through the mucosa. The power control box then decreases the power to a certain maximum power determined by the user. This prevents inadvertent cutting or damage to the deeper tissue of the body part. In another embodiment, the power control box may detect movement of the resection device to control the current or RF flow. In yet another embodiment, the power control box may also limit the maximum current flow by dumping excess current or FR flow to ground if the user inadvertently sets the power to a dangerous level.

[0033] Embodiments of the present invention further provide for methods of resecting affected tissue and promoting hemostasis to blood vessels. As illustrated in Figs. 4 and 5 and described below, these exemplary embodiments of the invention are described with reference to the resection of tissue in an esophagus. However, those of ordinary skill in the art will realize that the methods may be used to resection tissue in other parts of a patient's body. For example, similar methods may be used to remove sessile polyps or other tissue where the depth of cut in important to control.

[0034] Fig. 4 is an illustration of the resection device in a patient's esophagus and Fig. 5 is a block diagram illustrating a method of the present invention. The endoscope 32 and resection device 10 are inserted into a patient's 52 esophagus 54 at 70 using methods that are well known to those of ordinary skill in the art. The conducting element of the resection device 10 is positioned adjacent the tissue to be excised at 72. The power source 36 may be activated at 74 with the use of a foot pedal 56 to provide energy to the conducting element.

[0035] The amount of power required will vary depending on the tissue excised. However, for the excise of tissue in the esophagus, the power may be in a range of 20-300 Watts. It was determined that in this power range, non-affected tissue was not cut, but affected tissue was easy to cut into and to separate from its underlying support tissue.

[0036] As current is created by the power source to the resection device and as the resection device is moved between the affected and unaffected tissue, steam is created. The tissue is dissected utilizing the steam that is created by the resistive heating of the conducting element and/or the plasma field. It has been determined that the impedance of the mucosa and submucosa varies, possibly due to the greater percentage of moisture within the mucosa. This moisture difference results in a higher impedance in the submucosa and therefore less current flows to the submucosa. It is this impedance difference that allows the resection device to cut through the affected tissue and not damage the submucosa. Thus, the present invention provides for a safe way to excise tissue without cutting or damaging the deeper structures of the body part.

[0037] The resection device is moved along the esophagus lining at 76 and as discussed above, should be continually moved to prevent damage or cutting of the esophagus. The user may visually watch the endoscopic images as the resection device is moved along the esophagus to ensure good contact between the conducting element and the esophagus lining. When the desired tissue is excised and cut, the power source is deactivated at 78 by releasing the foot pedal 56. The excised tissue, endoscope, and resection device are then withdrawn from the patient at 80. The excised tissue may be attached naturally to the conducting element and thus withdrawn when the endoscope is withdrawn. However, the tissue may also be extracted with graspers. If additional tissue needs to be excised, the method is repeated at 82.

[0038] Embodiments of the present invention were tested in the esophagus of an animal. The resection device was attached to an RF electrosurgical generator and advanced into the esophagus. The RF energy was activated and a cut was made to separate the mucosa from the submucosa and deeper tissues of the esophagus. A clear and decisive separation of the mucosal tissue from the submucosa was obtained. Another similar excision was performed next to the initial excision and similar results were obtained. The esophagus was then excised and opened for analysis. It was clear that there were no perforations or burns to the esophagus and that the surface of the esophagus was completely denuded of mucosa.

[0039] While embodiments and applications of this invention have been shown and described, it would be apparent to those skilled in the art having the benefit of this disclosure that many more modifications than mentioned above are possible without departing from the inventive concepts herein. The invention, therefore, is not to be restricted except in the spirit of the appended claims.